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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

**Reporting of Pregnancy Success Rates from Assisted
Reproductive Technology (ART) Programs; Clarifications and
Modifications**

AGENCY: Centers for Disease Control and Prevention (CDC),
Department of Health and Human Services (HHS)

ACTION: Notice

SUMMARY: The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces clarification and modification of certain definitions used for reporting of pregnancy success rates from assisted reproductive technology (ART) programs as required by the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA). These clarifications and modifications are based on inquiries and comments to CDC after the publication of the Final Notice on August 26, 2015. All comments were reviewed and carefully considered

in developing the final definition to better assist ART clinics in reporting accurate data to CDC.

FOR FURTHER INFORMATION CONTACT: Jeani Chang, Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, MS-74, Atlanta, Georgia 30341. Phone: (770) 488-6370. E-mail: artinfo@cdc.gov.

SUPPLEMENTARY INFORMATION: On August 26, 2015, HHS/CDC published a notice in the *Federal Register* (80 FR 51811) announcing the overall reporting requirements of the National ART Surveillance System (NASS). The notice describes who shall report to HHS/CDC; the process for reporting by each ART program; the data to be reported; and the contents of the published reports.

This notice includes clarification and modification of certain definitions used for reporting of pregnancy success rates from assisted reproductive technology (ART) programs, reporting requirements and responsibilities, and data validation.

CLARIFICATION AND MODIFICATION:

Section J. Definitions:

Current: Gestational carrier (sometimes referred to as a gestational surrogate)—A woman who gestates an embryo that did not develop from her oocyte, with the expectation of returning the infant to its intended parent(s). NOTE: For female same sex couples, the woman who will carry the pregnancy should be identified as the patient and a separate cycle should be reported if donor oocytes are used, even if the patient's partner is the source of the oocytes. If a gestational carrier is used, one cycle is reported for fresh embryo cycle; two cycles should be reported for frozen embryo cycle (one for the oocyte retrieval and one for the embryo transfer).

Modification: Gestational carrier—A woman who gestates an embryo that did not develop from her oocyte, with the expectation of returning the infant to its intended parent(s). If a gestational carrier is used, one cycle should be reported for fresh oocyte cycles; at least two cycles should be reported for fresh embryos created from frozen/thawed oocytes or frozen/thawed embryos (one for the oocyte retrieval and one for each cycle conducted with the intent to transfer). NOTE: For female same sex couples, if one partner will carry the pregnancy, the partner who will carry the pregnancy should be identified as the patient.

Current: *Oligospermia*—Semen with a low concentration of sperm. Severe oligospermia is defined by <5 million spermatozoa per mL; moderate is defined by 5-15 million spermatozoa per mL.

Modification: *Oligozoospermia*—Semen with a low concentration of sperm. Severe oligozoospermia is defined by <5 million spermatozoa per mL; moderate is defined by 5-15 million spermatozoa per mL.

Addition: *Minimal stimulation protocol* — generally includes the use of oral medications, such as clomiphene citrate, followed by a low dose of injectable gonadotropin and an hCG trigger shot or just the hCG trigger shot.

Addition: *Cigarette smoking*—Includes smoking of combustible tobacco products, such as cigarettes, cigars, cigarillos and little cigars; does not include electronic cigarettes.

Date: December 12, 2016

Sandra Cashman

Executive Secretary

Centers for Disease Control and Prevention

